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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,761	09/04/2003	Dennis Ausiello	17509-0065	6913

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EXAMINER

MACNEILL, ELIZABETH

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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10/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/654,761

Applicant(s)

AUSIELLO ET AL.

Examiner

Elizabeth R. MacNeill

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-21, 24, 27, 32, 34-36 and 38-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-21, 24, 27, 32 and 34-36, 38-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1,12,17-20,24,27,32, and 34-36, 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (US 6,349,232) in view of Cheikh (US 5,660,846).

Gordon teaches and implantable (Col 4 lines 45-51) medical device for controlled delivery of a medical substance with a plurality of reservoirs (270), a release system (medical substance), with discrete reservoir caps (not labeled, Figures 9-11D), which are disintegrated by means of electrothermal ablation (resistive heating by 272/271, see Cols 8 and 9). Sensor (169) may also be included in the device. As to claim 34-36,38-40, see leads I and j, and also element 272 which has both input (to the resistor) and output (from the resistor).

Gordon does not disclose the delivery of parathyroid hormone.

Cheikh teaches the delivery of a parathyroid hormone from an implantable device (Col 7). It would have been obvious to one of ordinary skill in the art at the time the invention was made to choose the parathyroid hormone to deliver from the device of Gordon in order to provide appropriate medical treatment to the patient.

Art Unit: 3767

3. Claims 2-10 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon and Cheikh as applied above, and further in view of Rubin, et al., "The Potential of Parathyroid Hormone as a Therapy for Osteoporosis," Int. J. Fertil. 47(3): 103-15 (2002) (cited by applicants; hereinafter "Rubin").

Gordon and Cheikh teach the device and method as above, but fail to teach the details of the parathyroid treatment.

Rubin suggests the use of parathyroid hormone to treat osteoporosis. Rubin discusses dosage, length of therapy and the use of bone resorption inhibitors as well. It would have been obvious to one of ordinary skill in the art to modify the system disclosed by Gordon and Cheikh, by including parathyroid hormone as the release system in order to provide therapy for those suffering from osteoporosis.

4. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon and Cheikh, further in view of U.S. Patent No. 6,011,011 to Hageman.

Gordon and Cheikh disclose the claimed invention as shown above except for an excipient of polyethylene glycol. Hageman teaches the use of polyethylene glycol as an excipient with parathyroid hormone. See col. 3, line 28 through col. 4, line 12. It would have been obvious to one of ordinary skill in the art to modify the invention of Gordon and Cheikh and Rubin by including polyethylene glycol as an excipient in order to provide a sustained or prolonged release of the hormone.

Response to Arguments

Applicant's arguments filed 24 September 2007 have been fully considered but they are not persuasive. In response to applicant's argument that the references fail to show

Art Unit: 3767

certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the reservoir cap must be both a barrier and resistive heating element) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The walls of the reservoirs are illustrated as distinct from each other in Figs 9 and 10, and also discrete caps (289) are shown in Fig 12A which are ruptured by "electrical communication with a heating element." In order for the device to function, the walls at the "top" or exposed side of the device *must* be ruptured for the device to deliver the medication. Therefore, the "top" walls of the reservoirs (shown as discrete in Fig 9-10) are considered discrete reservoir caps. Further, the "means for" identified in the specification (P0020) "comprises a power source for passing an electric current or Potential through the reservoir caps." The resistor 272 meets this description by passing current through the resistor adjacent the cap to heat or ablate it.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 3767

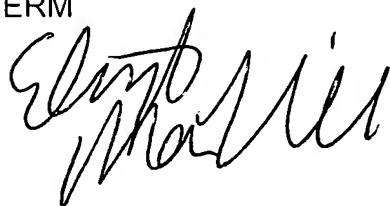
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM



KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

